



LÄKEMEDELSVERKET  
MEDICAL PRODUCTS AGENCY

Pharmacovigilance  
Jolanta Gulbinovic

Date: 2006-11-28 Dnr: 2154:2006/72930

Merck Sharp & Dohme (Sweden) AB  
Box 7125  
192 07 Sollentuna

PSUR  
30-NOV  
MAX VÄRSLAM

### After control of medicinal product

ASP no.	Swedish MA-number	Medicinal Product
1997-0007	13483	Propecia, 1 mg tablet
1998-0015	14386	Capipro, 1 mg tablet

### Regarding reversibility of adverse reactions related to the male reproductive system

In the SmPC for Propecia it is stated that adverse reactions usually have resolved while on treatment or after cessation of therapy with Propecia. This was supported by clinical trial data presented before approval.

After the approval reported spontaneous reports received from HCP have regularly been presented within the PSUR's of the MAH. The most frequently reported adverse reactions in the last PSUR were erectile dysfunction, gynaecomastia and testicular pain.

Within the cumulative submitted documentation no new data has been presented indicating an increasing problem with male reproductive system symptoms (erectile dysfunction, disturbance of ejaculation including decreased volume of ejaculate, testicle pain) not being reversible after cessation of therapy.

The follow-up of spontaneous cases of reported ADR's related to the male reproductive system and associated to intake of finasteride in the national database SWEDIS has only revealed two reports where reversibility of the symptoms was not demonstrated. This concerned the 5 mg dose of finasteride (Proscar) and was related to treatment of prostatic symptoms in two men >60 years.

However, it has come to the knowledge of MPA that information of remaining problems from the male reproductive system after cessation of therapy with Propecia is spread over Internet sites.

In view of this information the MAH is requested to within the coming PSUR with data lock point 2006-11-06 and with submission 5<sup>th</sup> of January 2007, in addition to previous issues raised in the last PSUR, also submit an amalgamated listing of all reported cases of ADR's related to the male reproductive system after the approval and present any possible knowledge of the outcome in terms of reversibility of symptoms for individual cases.

Please refer to the reference (Dnr) in all correspondence regarding this matter.

On behalf of the Medical Products Agency,

*[Signature]*  
Marie Andersson on behalf of Jolanta Gulbinovic

Spont, HCP.

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